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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/378,045 08/20/99 RAUCH

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022932
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HM12/0705

EXAMINER

BASIL N

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/378,045

Applicant(s)

Rauch et al

Examiner

Nirmal. S. Basu

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 15, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

1. *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- 5 I. Claims 1-16, drawn to a purified TRAIL receptor, classified in class 530, subclass 350.
- II. Claims 17-37, drawn to the polynucleotide sequence encoding the TRAIL receptor vectors encoding, cells containing the afore mentioned expression vectors, classified in class 536, subclass 23.5, for example .
- 10 III. Claims 38-39 drawn to antibody which binds to TRAIL receptor, classified in class 530, subclass 387.9, for example.

The inventions are distinct, each from the other because of the following reasons:

15 The proteins of Invention I are related to the nucleic acids of Invention II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in claim 10. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for the processes other than the production of the protein, such as
20 nucleic acid hybridization.

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The proteins of Invention I are related to antibodies of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary steric complementary of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right or in assays for the identification of agonists of the receptor protein.

The products of Inventions II and Invention are distinct from each other because they are physically and functionally distinct chemical entities and are capable of separate use and manufacture, for example, the TRAIL receptor may be produced from the DNA encoding it.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper. A search of the art for Inventions I-III would not be co-extensive with each other. Because the searches required for these inventions are not co-extensive an examination of the materially different, patentably distinct inventions in a single application would constitute a serious burden on the examiner.

During a telephone conversation with Kathryn Anderson on 5/16/01 a provisional election was made with traverse to prosecute the invention of Group III, claims 38-39. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Specification

2. The disclosure is objected because of the following informalities and appropriate correction is required:

Applicants are required to use the heading "Brief Description of the Drawings" to describe the drawings. See MPEP 608.01(f). The applicant has used the heading "Brief Description of the Figures" on page 2.

Sequence Rules

3. The instant application is not fully in compliance with the sequence rules, 37 CFR §§ 1.821-1.825. Specifically, the application improperly discusses sequences without reference to the designated sequence identifier (ie. SEQ ID NO:). See CFR § 1.821(d). Specifically, a sequence is disclosed in Figure 1, 5A and 5B without reference to a sequence identifier in the Figure itself or in the respective Brief Description of Drawings.

Appropriate correction is required.

During a telephone conversation with Kathryn Anderson on 6/20/01, Kathryn Anderson stated the sequences in instant application were the same as in parent application 08/883,036. The Examiner

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has used the sequences in parent application number 08/883,036 to do a sequence search for SEQ ID NO:3. The claims will be examined on the basis of said sequence search. The sequences in instant application are still not in compliance with the sequence rules for reason, stated in paper number 8, 03/27/01. The sequence error report is attached for Applicants convenience.

5 The Applicant can transfer the sequences from parent Application 08/883,036 into instant application. The following paragraph, or language having the same effect, can be used to invoke the procedure of 37 CFR section 1.821(e) in which an identical computer readable form from another applications used in a given application. The paragraph should be incorporated into a separate paper to be submitted in the given application:

10 The computer readable form in this application, 08/883,036 is identical with that filed in Application Number 09/378,045, filed August 20, 1999. In accordance with 37 CFR 1.821 (e), please use the [first-filed, last-filed or only, whichever is applicable] computer readable form filed in that application as the computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in the application number and filing date
15 for the computer readable form that will be used for the instant application. A paper copy of the Sequence Listing is [included in the originally-filed specification of the instant application, included in a separately filed preliminary amendment for incorporation into the specification, whichever is applicable].

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If Applicant does not transfer the Sequence listing from parent application then the errors in sequence listing report must be corrected. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825).

Claim 38 is objected to as being of improper dependent form. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 38 is dependent on non-elected claim 5.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 38 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Arizumi et al. (U.S. Pat. No. 6,046,158).

Arizumi teaches the production of monoclonal antibodies against dectin-1 and dectin-2. Dectin-1 comprises the amino acid sequence of SEQ ID NO:2. SEQ ID NO:2 disclosed by Arizumi contains a sequence, "Val Val Ala Ala val Leu" at position 59-64, which is identical to amino acids 41-46 present in SEQ ID NO:2 of instant application. Therefore, the monoclonal antibody raised to fragments comprising or consisting of "Val Val Ala Ala Val Leu" would reasonably be expected

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to bind to the TRAIL-R of claim 5, absent evidence to the contrary, thereby meeting the limitations of claims 38 and 39.

Advisory Information

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

10 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.


Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

15 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi

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20 July 1, 2001


YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600